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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,970	08/22/2003	Morteza Naghavi	D8562-16	8386

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EXAMINER	
LAURITZEN, AMANDA L	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,970	NAGHAVI ET AL.	
	Examiner	Art Unit	
	Amanda Lauritzen	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,35-39,41-50,52 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,35-39,41-50,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to communications filed 19 January 2011. The claims have been amended to absolve the previously raised new matter issues, but claim 44 has been amended to specify forming first and second maps of the plurality of sections of the coronary arteries..." but the specification is not particular to forming first and second (distinct) maps, but only that a map is formed.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant contests that the assessment of artery calcification in Hu does not include assessing the patient's risk of cardiovascular disease. Examiner disagrees. Hu explicitly calculates calcium density and methods include acquiring images of the artery such that an attenuation profile is divided into individually quantifiable (scorable) regions or spots within the image, as in col. 1, lines 60-63 and col. 3, lines 48-53. Additionally, a total calcium score is determined by a summation of each of the scores of the individual adjacent regions, which is directly indicative of a risk. For example, if scorable regions are of uniform size, and a higher density of plaque indicates a higher score for the individual region, the summation of the scores will in fact serve as a risk indication, as among a large population, a lower risk (score) will be characterized as generally having lower scores over a smaller region of calcified arterial wall (indicating less plaque), while a higher risk (score) will be characterized as generally having higher scores over a larger continuous region of an arterial wall (and likewise indicates more

plaque). A section of artery with no calcified plaque is understood by convention to have a calcium score of 0, and thus will not contribute to the patient's overall risk when summed for calculation of the total calcium score. Additionally, it is noted that a calcium score is defined within the relevant arts as a quantitative indicator of the likelihood for future heart disease events, such as heart attacks, as defined by the National Institutes of Health (www.nih.gov). By this showing, applicant's statement that the methods of Hu do not indicate a patient's risk is erroneous.

Examiner again points out that changes in density are at the very least qualitatively indicated within the images generated of the arterial wall(s) in the method of Hu. Changes in density will undoubtedly be visible within the image. The attenuation profile directly corresponds to the density of plaque and visually indicates changes to the user. Applicant does not claim quantitatively indicating changes in density and therefore the rejection is maintained.

Additionally, the attenuation image(s) will indicate the progression of plaque or will qualitatively show the plaque formation and where or how it has settled on the arterial wall. By this it will make clear where areas of reduced blood flow are occurring, for which more plaque has settled to effectively decrease the elasticity of the arterial wall and/or reduce the diameter of the artery (or the volume through which blood can flow). These visual assessments of the image by the user all indicate a risk in a qualitative capacity and the overall calcium score indicates a quantitative risk metric. The risk determined in applicant's invention has not been claimed in such a way that it would exclude either of Hu's qualitative or quantitative risk assessments. If applicant's risk assessment(s) are different, they have not been set forth in the claims in such a way as to clearly distinguish from the prior art.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 44-50, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 44 has been amended to specify forming first and second maps of the plurality of sections of the coronary arteries..." but the specification is not particular to forming first and second (distinct) maps, but only that a map is formed. Applicant has not provided a clear showing that this feature was owned at the time the application was filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2.1 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2.2 Claims 1, 38, 39, 40, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Rather et al. (US 6,385,474).

Hu et al. disclose a method for detecting coronary artery calcification by computed tomography in one of multi-slice helical reconstruction and electron beam computed tomography in a system with multiple arrayed detectors (col. 1, lines 13-15; 42-62). Images are reconstructed based on the attenuation profile (col. 1, lines 19-21), with visualization of data giving rise to mapping sections of arteries or vessels of interest. The attenuation profile aids in identifying calcification (or scorable regions of interest or spots within the image) to determine calcification density, as in col. 1, lines 60-63 and col. 3, lines 48-53. A total calcium score is determined by summing the scores of the individual regions of interest, which indicates a risk as claimed (in this case, a quantitative risk). A density score is determined for each pixel within a region of interest (spot) and thus any changes in density will be observable, as in col. 4, lines 26-33. In one example, a spot or scorable region within an image is comprised of 100 pixels, as in col. 4, lines 30-33. The spots are visualized within an image and this accommodates assessing the location and shape of the spots and indicates risk qualitatively. Plaques are understood to accumulate in both circular and angular formations. The pattern of the scorable regions (spots) will be visible within the image, which is a qualitative indication of relative cardiovascular risk (provided in addition to the quantitative risk calculation described above). Both variations in

texture (rough or smooth) and distribution will be visible as variations in brightness within the scorable region or spot, which reflects variation in attenuation of the return data (and qualitatively indicates a risk). The method is disclosed to produce data for at least one or more regions of interest within the scorable region, as in col. 4, lines 56-60, abstract. In cases in which more than one region of interest is assessed, a variation in calcium density will be observable among the spots.

The total calcium score determined in the method of Hu et al. is a general quantitative indicator for disease risk assessment. Calculation of x-ray attenuation coefficients is provided in the form of CT numbers that are used in threshold comparison (col. 4, lines 15-36, in which a threshold of 130 HU is selected).

Hu et al. teach qualitative assessment of the distribution of plaques, but Rather et al. teach localizing features within a region of a CT image, for example, and collect information related to the scattering effects of the plaque in the form of reflection, transmission and diffraction from features or spots within the object under examination, which provides a quantitative measure of risk and calcium distribution, as in col. 2, line 44 – col. 3, line 3. Additionally, the pattern of spots will be visible within the image.

It would have been obvious to one ordinarily skilled in the art at the time of invention to incorporate assessment of scattering properties of a region of interest, as taught in Rather et al., in the method of Hu et al., in order to localize features or spots within the image.

2.3 Claims 35, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Rather et al. (US 6,385,474), as applied to claim 1 above, further in view of Tierstein et al. (US 2001/0018042).

The combination of Hu and Rather et al. includes all features of the invention as substantially claimed, as detailed above, and while changes in density will be visible with the thresholding to identify scorable regions (taken to be areas of greater risk of cardiovascular disease) in the method of Hu, it is not particularly disclosed that an change in density is identified as a high risk region; however, Tierstein et al. disclose CT visualization for detection of vulnerable plaques, in which likelihood or risk of a plaque destabilizing is assessed, as in [0007], [0071]. The methods are specific to identifying plaques most likely to rupture, or higher risk plaques, which are marked by a juncture in which pools of cholesterol abut areas of more fibrous plaques, as in [0015]. Identifying such a juncture is identifying an area of abrupt change. It is additionally disclosed that irregular plaque profiles are an indicator of thrombosis or a likelihood of complete occlusion, as in [0011], [0023]. It would have been obvious to one ordinarily skilled in the art at the time of invention to assess the CT images for areas of abrupt change in the arterial wall, as taught by Tierstein et al., in order to identify a potential for thrombosis or a complete occlusion, as in [0011].

2.4 Claims 43, 44, 48, 49, 50, 51, 52, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. in view of Rather et al. and O'Brien et al. (US 2004/0057955).

Hu et al. disclose a method for detecting coronary artery calcification by computed tomography in one of multi-slice helical reconstruction and electron beam computed tomography

in a system with multiple arrayed detectors (col. 1, lines 13-15; 42-62). Images are reconstructed based on the attenuation profile (col. 1, lines 19-21), with visualization of data giving rise to mapping sections of arteries or vessels of interest. The attenuation profile aids in identifying calcification (or scorable regions of interest or spots within the image) to determine calcification density, as in col. 1, lines 60-63 and col. 3, lines 48-53. A total calcium score is determined by summing the scores of the individual regions of interest, which indicates a risk as claimed. A density score is determined for each pixel within a region of interest (spot) and thus any changes in density will be observable, as in col. 4, lines 26-33. In one example, a spot or scorable region within an image is comprised of 100 pixels, as in col. 4, lines 30-33. The spots are visualized within an image and this accommodates assessing the location and shape of the spots. Plaques are understood to accumulate in both circular and angular formations. The pattern of the scorable regions (spots) will be visible within the image. Both variations in texture (rough or smooth) and heterogeneity will be visible as variations in brightness within the scorable region or spot, which reflects variation in attenuation of the return data. The method is disclosed to produce data for at least one or more regions of interest within the scorable region, as in col. 4, lines 56-60, abstract. In cases in which more than one region of interest is assessed, a variation in calcium density will be observable among the spots.

The total calcium score determined in the method of Hu et al. is a general quantitative indicator for disease risk assessment. Calculation of x-ray attenuation coefficients is provided in the form of CT numbers that are used in threshold comparison (col. 4, lines 15-36, in which a threshold of 130 HU is selected).

Hu et al. do not specifically address determining a scatterness for each calcified spot, but Rather et al. teach localizing features within a region of a CT image, for example, and collect scattering information in the form of reflection, transmission and diffraction from features or spots within the object under examination, as in col. 2, line 44 – col. 3, line 3. The pattern of spots will be visible within the image. It is understood that patterns associated with the density gradient, such as a higher density core or outer ring, will be apparent within the image and reflected in the attenuation data.

It would have been obvious to one ordinarily skilled in the art at the time of invention to incorporate assessment of scattering properties of a region of interest, as taught in Rather et al., in the method of Hu et al., in order to localize features or spots within the image.

The combination of Hu and Rather et al. includes all features of the invention as substantially claimed, but is not specific to scanning at first and second times; however, O'Brien et al. teach assessing aortic valve calcium for both an initial scan and a follow up scan, as in [0086]. A comparison is made such that any change in calcium accumulation over time can be assessed, as in [0089], which presumably involves storing or saving data resulting from a first scan for subsequent access. It would have been obvious to one ordinarily skilled in the art at the time of invention to collect data over two separate diagnostic scans at first and second times, such that the progression of plaque over the interval can be assessed, as taught in O'Brien et al. It is understood that the assessment of a calcified region or a lesion at a second time will offer an indication as to the outcome or resulting state of any lesion(s) localized in a first scan.

Regarding claim 53, a progression of plaque is determined in O'Brien et al., as in [0089], in which accumulation over time is assessed between first and second scans. O'Brien et al.

additionally teach statistically analyzing the data to assess progression of calcification, as in [0085].

2.5 Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Rather et al. (US 6,385,474), as applied to claim 1 above, further in view of Zeng et al. (US 2003/0099385).

The combination of Hu and Rather et al. includes all features of the invention as substantially claimed, including localizing atherosclerotic plaques within images, but is not specific to locating the lesions with respect to anatomical landmarks associated with the heart; however, Zeng et al. teach segmenting lesions within CT images to determine their location(s) with respect to various landmarks, as in [0051]. It would have been obvious to one ordinarily skilled in the art at the time of invention to include referencing plaque distance from the heart or an anatomical feature of the heart, such that lesion locations can be determined with respect to identifiable structures also appearing in the image.

2.6 Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. in view of Rather et al. and O'Brien et al., as applied to claim 43 above, further in view of Zeng et al. (US 2003/0099385).

The combination of Hu, Rather and O'Brien et al. includes all features of the invention as substantially claimed, including localizing atherosclerotic plaques within images, but is not specific to locating the lesions with respect to anatomical landmarks associated with the heart; however, Zeng et al. teach segmenting lesions within CT images to determine their location(s)

with respect to various landmarks, as in [0051]. It would have been obvious to one ordinarily skilled in the art at the time of invention to include referencing plaque distance from the heart or an anatomical feature of the heart, such that lesion locations can be determined with respect to identifiable structures also appearing in the image.

2.7 Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Rather et al. (US 6,385,474), as applied to claim 1 above, further in view of Kaufman et al. (US 2003/0018245).

The combination of Hu and Rather et al. includes all features of the invention as substantially claimed, including analyzing CT data associated with images of atherosclerotic plaques, but is not specific to statistical assessments; however, Kaufman et al. teach localization and analysis of lesions within CT images with methods applicable to calcium assessment and scoring, as in the abstract and [0050], and detail statistical analysis of the attenuation data, including identification of a range, mean and standard deviation, as in [0014], [0049], [0066]-[0067], [0123], [0133], [0136] and [0143]. It would have been obvious to one ordinarily skilled in the relevant art at the time of invention to include calculation of statistics for each lesion appearing in the image in order to garner useful information about each nodule within an image.

2.8 Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. in view of Rather et al. and O'Brien et al., as applied to claim 43 above, further in view of Kaufman et al. (US 2003/0018245).

The combination of Hu, Rather and O'Brien et al. includes all features of the invention as substantially claimed, including analyzing CT data associated with images of atherosclerotic plaques, but is not specific to statistical assessments; however, Kaufman et al. teach localization and analysis of lesions within CT images with methods applicable to calcium assessment and scoring, as in the abstract and [0050], and detail statistical analysis of the attenuation data, including identification of a range, mean and standard deviation, as in [0014], [0049], [0066]-[0067], [0123], [0133], [0136] and [0143]. It would have been obvious to one ordinarily skilled in the relevant art at the time of invention to include calculation of statistics for each lesion appearing in the image in order to garner useful information about each nodule within an image.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amanda Lauritzen/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737